

Translation

PATENT COOPERATION TREATY

PCT/JP2003/013063



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

08 APR 2004

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| Applicant's or agent's file reference<br>C1-A0220P  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |  |
| International application No.<br>PCT/JP2003/013063  | International filing date (day/month/year)<br>10 October 2003 (10.10.2003)  | Priority date (day/month/year)<br>11 October 2002 (11.10.2002) |
| International Patent Classification (IPC) or national classification and IPC<br>C07K 16/18, C12P 21/08, A61K 39/395, A61P 35/00, 37/02, 43/00 |   |  |
| Applicant<br>CHUGAI SEIYAKU KABUSHIKI KAISHA  |   |  |

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|---|--|
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>   |  |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> |  |

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|--|--|
| Date of submission of the demand<br>10 October 2003 (10.10.2003) | Date of completion of this report<br>06 February 2004 (06.02.2004) |
| Name and mailing address of the IPEA/JP                          | Authorized officer   |
| Facsimile No.  | Telephone No.  |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/013063

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/JP 03/13063

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

|                               |        |      |     |
|-------------------------------|--------|------|-----|
| Novelty (N)                   | Claims | 4-23 | YES |
|                               | Claims | 1-3  | NO  |
| Inventive step (IS)           | Claims | 5-23 | YES |
|                               | Claims | 1-4  | NO  |
| Industrial applicability (IA) | Claims | 1-23 | YES |
|                               | Claims |      | NO  |

### 2. Citations and explanations

Document 1: Blood, 1997, Vol. 90, No. 9, pp. 3629-3639

Document 2: J. Exp. Med., 1995, Vol. 181, No. 6, pp.  
2007-2015

Document 3: Int. Immunol., 1998, Vol. 10, No. 9, pp.  
1347-1358

Document 4: Mol. Immunol., 1999, Vol. 36, No. 6, pp.  
387-395

Document 5: Biochem. Biophys. Res. Commun., 1999, Vol.  
258, No. 3, pp. 583-591

Document 6: Blood, 1999, Vol. 93, No. 11, pp. 3922-3930

#### Claims 1 to 3

Claims 1 to 3 lack novelty and do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Document 1 indicates monovalent Fab' fragments from an antibody against the  $\alpha 1$  domain of HLA class IA molecules from humans. Therefore, the invention that is indicated in document 1 cannot be differentiated from the invention that is set forth in claims 1 to 3 of the present application.

Document 2 indicates Fab fragments from the antibody (RE2) against the  $\alpha 2$  domain of HLA class IA molecules from mice. Therefore, the invention that is indicated in

document 2 cannot be differentiated from the invention that is set forth in claims 1 to 3 of the present application.

Document 3 indicates monovalent Fab fragments from an antibody against the  $\alpha 3$  domain of HLA class IA molecules. Therefore, the invention that is indicated in document 3 cannot be differentiated from the invention that is set forth in claims 1 to 3 of the present application.

#### Claims 1 to 4

Claims 1 to 4 do not involve an inventive step in the light of documents 4 to 6 cited in the international search report. Documents 4 to 6 indicate the production of humanized antibodies from anti-HM1.24 antibodies that are obtained by immunizing Balb/c mice using human myeloma cells.

The feature of degrading an antibody is well known in the technical field in question; therefore, it would be easy for a person skilled in the art to produce antibody fragments by degrading the anti-HM1.24 antibodies that are indicated in documents 4 to 6.